K013725

JAN 3 0 2002

510(k) Summary

1. Name/Address of Submitter: Meditron AS
   Leangbukta 40
   N-1392 Ventre
   Norway

2. Contact Person: Charles H. Kyper, RAC
   Kyper & Associates
   (919) 960-0049

3. Date Summary Prepared: November 7, 2001

4. Device Name: Meditron II thestethoscope system

5. Predicate Devices: CADItec AG CADIscope Electronic Stethoscope with Integrated ECG (K990809)
   Meditron thestethoscope system (K991367)
   Kendall-LTP Disposable ECG Electrode (K953649)

6. Device Description and Intended Use:

   The Meditron electronic stethoscope system is intended for use as a diagnostic aid in patient diagnosis, treatment and monitoring. It amplifies, records, stores, plays back, and transmits sounds associated with the heart, arteries, and veins and other internal organs. The present modification involves the addition of a 3-lead electrocardiograph to produce an ECG on the PC monitor to enable the health care practitioner to synchronize the phonocardiogram with the beginning of the heart cycle.

7. Brief Description of Nonclinical and Clinical Testing:

   The specifications and testing for biocompatibility, electrical safety, electro-Magnetic compatibility (EMC), and software verification/validation reference applicable FDA consensus standards. All product specifications were met. Clinical study information was not submitted for the purpose of demonstrating substantial equivalence to legally marketed electronic stethoscopes with an integrated ECG.

8. Conclusions Drawn:

   The indications for use are consistent with those for legally marketed electronic stethoscopes with an integrated ECG. Differences in technological characteristics are minor and do not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Meditron AS
c/o Mr. Charles H. Kyper, RAC
President and Founder
Kyper & Associates LLC
103 Nolen Lane
Chapel Hill, NC 27516

Re: K013725
Trade Name: Meditron II Thestethoscope System
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: November 7, 2001
Received: November 9, 2001

Dear Mr. Kyper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K013725

Device Name: Meditron II thestethoscope system

Indication for Use: Intended for use as a diagnostic aid in patient diagnosis, treatment, and monitoring. It amplifies sounds from the body's internal organs, mainly the heart and circulatory and respiratory organs. The system is includes a 3-lead electrocardiograph that produces a visual display of the electrocardiogram (ECG) on the PC monitor to enable the healthcare practitioner to synchronize the phonocardiogram with the beginning of the heart cycle. The ECG is not intended for diagnostic use. The system provides computer-aided recordings and storage of these sounds along with other patient information.

Concurrence of CDRH Office of Device Evaluation

Prescription Use ✓ **OR** **Over-the-counter Use** ____
(per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013725